Canada â€“ Patent Protection of Pharmaceutical Products
WT/DS114/R

Country: Canada
Region: Americas
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Court: World Trade Organization
Health Topics: Medicines

Facts

The European Communities and their member States challenged Sections 55.2(1) and 55.2(2) of the Patent Act of Canada, which created exceptions to the exclusive rights of patent owners, as violating provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS" or "TRIPS Agreement"). Under Article 28.1 of the TRIPS Agreement, parties were to ensure patent owners the right to exclude others from making, using, selling, offering for sale or importing the patented product during the term of the patent. According to Article 33 of the TRIPS Agreement, the term of patent protection had to last at least 20 years counted from the filing date of the application against which the patent was granted.

Sections 55.2(1) of Canada's Patent Act, known as the regulatory review exception, allowed third parties to make the patented product during the term of the patent, without the consent of the patent owner, for purposes of beginning the regulatory review and approval process, a process that could take up to 12 years in Canada. Section 55.2(2) of the Patent Act, known as the stockpiling exception, likewise allowed third parties to manufacture the patented product during the term of the patent without the consent of the patent owner for the purposes of storing the product for sale after the terms of the patent expired. Regulations promulgated pursuant to Section 55.2(2) allowed third parties to manufacture and store pharmaceutical products for up to six months prior to the expiration of the patent. The stockpiling exception was available only to persons who had previously invoked the regulatory review exception in Section 55.2(1).

The European Communities claimed that Sections 55.2(1) and 55.2(2) of the Patent Act violated TRIPS in the following ways:

1. Article 28.1 and Article 33 of TRIPS were breached because Canada allowed the manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder during the six months immediately prior to the expiration of the 20-year patent term;

2. Article 27.1 of TRIPS was breached because Canada treated patent holders in the field of pharmaceutical inventions less favourably than inventions in all other fields of technology; and

3. The provisions of Section 55.2(1) of Canada's Patent Act concerning activities related to the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder violated Article 28.1 of the TRIPS Agreement.

The European Communities and their member States requested that a Panel of the World Trade Organization examine the matter and order Canada to bring its domestic legislation into conformity with its TRIPS obligations.

Decision and Reasoning

The Panel held that the stockpiling exception of Article 55.2(2) of the Patent Act violated Article 28.1 of TRIPS because it infringed on a patent owner's exclusive patent rights. Canada argued that the stockpiling exception was valid pursuant to Article 30 of TRIPS, which allowed for limited exceptions to exclusive patent rights if "such exceptions [did] not unreasonably conflict with the normal exploitation of the patent and [did] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The Panel rejected this argument, holding that the stockpiling exception unreasonably prejudiced the interests of the patent holder by allowing third parties to make and use the patented product for six months prior to the expiration of the patent, with no limit on the amount of the product.
that could be made and stored.

Regarding the regulatory review exception of Article 55.2(1) of the Patent Act, the Panel held that this exception was a valid limited exception within the meaning of Article 30 of TRIPS. The Panel reasoned that the exception only provided for minimal curtailment of Article 28.1 rights. The Panel further held that, even if the regulatory review exception had a substantial economic impact on the patent holder, Article 30's requirement that any exception to exclusive patent rights be "limited" was not intended to address economic interests.

While Canada argued that it was clear from the drafting history of TRIPS, during which the United States had intended to secure its own regulatory review exception similar to the exception in Article 55.2(1), that such regulatory review exceptions were to be permitted under TRIPS, the Panel declined to consider this argument because there was no documented evidence of this negotiation.

Finally, the Panel concluded that there was no breach of Article 27.1 of TRIPS, and no discrimination against pharmaceutical inventions, because the European Communities could not demonstrate that the exceptions in Canada's Patent Act were limited to pharmaceutical products alone.

**Decision Excerpts**

"In the view of Canada, the italicized text of Article 7 above declares that one of the key goals of the TRIPS Agreement was a balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments. Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies. With respect to patent rights, Canada argued, these purposes call for a liberal interpretation of the three conditions stated in Article 30 of the Agreement, so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies." Para. 7.24.

"In the Panel's view, the question of whether the stockpiling exception is a 'limited' exception turns on the extent to which the patent owner's rights to exclude 'making' and 'using' the patented product have been curtailed. The right to exclude 'making' and 'using' provides protection, additional to that provided by the right to exclude sale, during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained. With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect." Para. 7.34.

"In view of Canada's emphasis on preserving commercial benefits before the expiration of the patent, the Panel also considered whether the market advantage gained by the patent owner in the months after expiration of the patent could also be considered a purpose of the patent owner's rights to exclude 'making' and 'using' during the term of the patent. In both theory and practice, the Panel concluded that such additional market benefits were within the purpose of these rights. In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward. In practical terms, it must be recognized that enforcement of the right to exclude 'making' and 'using' during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires. The repeated enactment of such exclusionary rights with knowledge of their universal market effects can only be understood as an affirmation of the purpose to produce those market effects." Para. 7.35.

"In the Panel's view, however, Canada's regulatory review exception is a 'limited exception' within the meaning of TRIPS Article 30. It is 'limited' because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products." Para. 7.45.

"A final objection to the Panel's general conclusion remains to be addressed. Although the point was raised only briefly in the parties' legal arguments, the Panel was compelled to acknowledge that the economic impact of the regulatory review exception could be considerable. According to information supplied by
Canada itself, in the case of patented pharmaceutical products approximately three to six-and-a-half years are required for generic drug producers to develop and obtain regulatory approval for their products. If there were no regulatory review exception allowing competitors to apply for regulatory approval during the term of the patent, therefore, the patent owner would be able to extend its period of market exclusivity, de facto, for some part of that three to six-and-half year period, depending on how much, if any, of the development process could be performed during the term of the patent under other exceptions, such as the scientific or experimental use exception. The Panel believed it was necessary to ask whether measures having such a significant impact on the economic interests of patent owners could be called a 'limited' exception to patent rights. After analysing all three conditions stated in Article 30 of the TRIPS Agreement, the Panel was satisfied that Article 30 does in fact address the issue of economic impact, but only in the other two conditions contained in that Article. As will be seen in the analysis of these other conditions below, the other two conditions deal with the issue of economic impact, according to criteria that relate specifically to that issue. Viewing all three conditions as a whole, it is apparent that the first condition ("limited exception") is neither designed nor intended to address the issue of economic impact directly." Paras. 7.48-7.49.

"With regard to the first issue - the actual effects of the measure -, the EC had argued that, despite its potentially broad coverage of many industries, the exception created by Section 55.2(1) had 'in effect' applied only to pharmaceutical patents. The Panel received no systematic information on the range of industries that have actually made use of Section 55.2(1). In the absence of such information, the critical question was whether there was some practical reason why the regulatory review exception would in reality work only to the disadvantage of producers of patented pharmaceutical products. The Panel asked the parties for an explanation of any practical considerations that would limit the scope of application of Section 55.2(1) to pharmaceutical products, but no such explanation was provided. Nor was the Panel able to find such a practical reason from the information before it. The Panel concluded that the EC had not demonstrated that Section 55.2(1) had had a discriminatory effect limited to patented pharmaceutical products." Para. 7.102